

Results of Program Analysis

FDA RADIATION CONTROL PROGRAM

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STAKEHOLDER NEEDS

Reliable Data

Risk Perspective

Guidelines

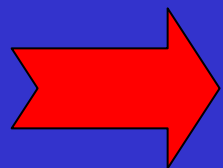
Most Important to Do

From TEPRSSC

- **Provide national uniformity, consistency**
- **Conduct in-depth characterization of radiation emission from products**
- **Analyze trends (denominators, incidence, problems) - ionizing, nonionizing, new technology**
- **Give characterizations and trends to States**
- **Train States, industry, and 3rd parties**
- **Conference with industry, academia, etc. to collect information**

Results of Program Analysis

FDA RADIATION CONTROL PROGRAM



National Direction & Uniformity
Emissions & Exposure Trends
Training

STAKEHOLDER NEEDS

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Goals by Process Function

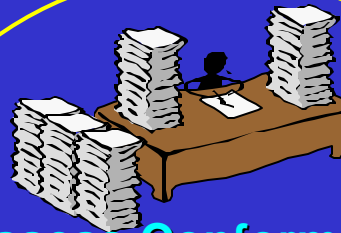
VISION FOR CDRH

Leading a national radiation control program
to protect and promote public health



Set Criteria

→ **Clear criteria**
Risk/Benefit
Practical
→ **Dynamic**



Assess Conformance

→ **Consistent, Even-handed**
Highest Priority Products



Police

→ **Remove Unsafe**
Correct Non-
conformance



Generate New Information

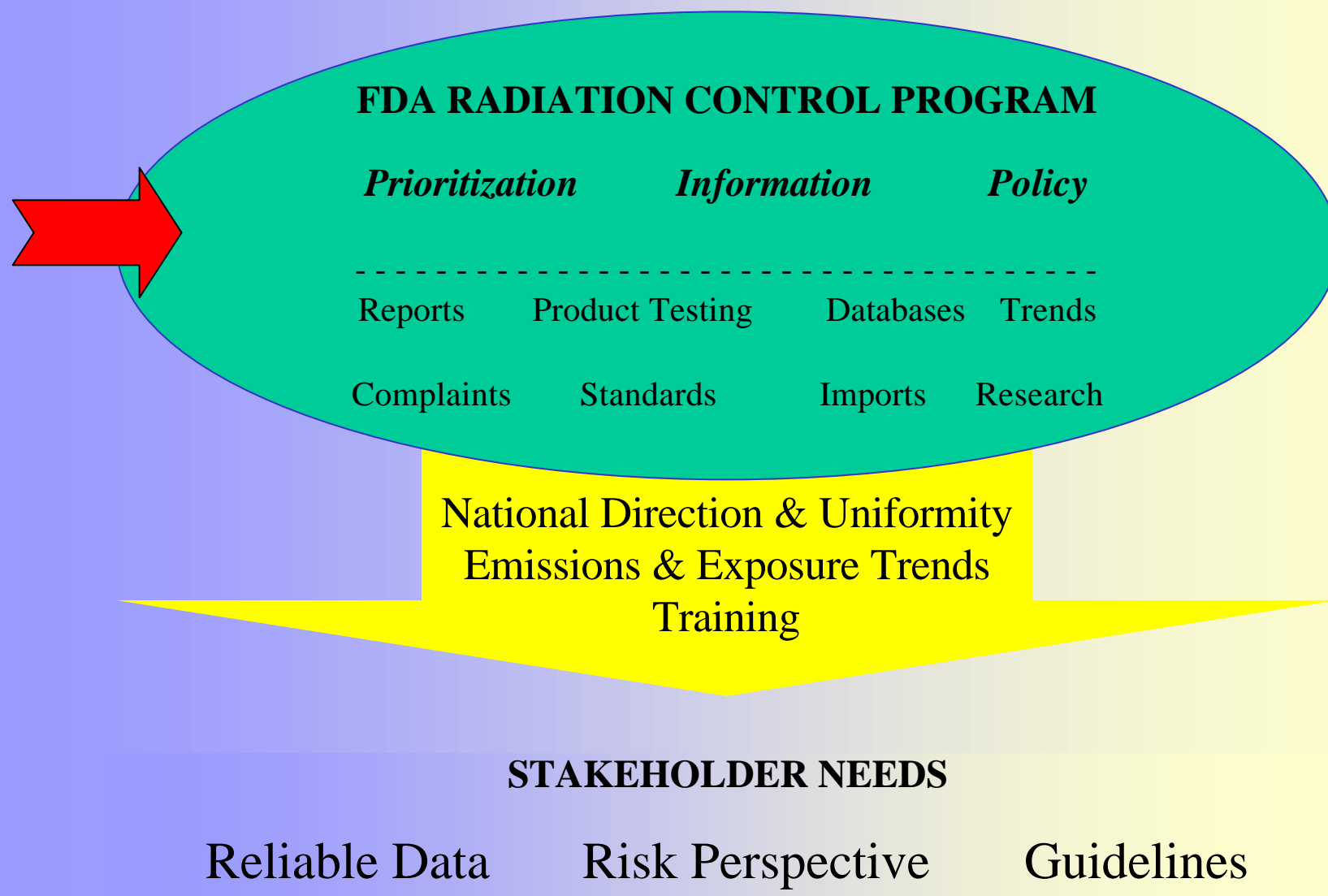
→ **Up-to-date Info**
Sci. Understanding
Sound Decisions



Disseminate Info

→ **Adequate Amount**
Targeted
Elicit Behaviors

Results of Program Analysis



Program Reengineering

MANAGEMENT

PRIORITIZATION (Products & Processes)

Reengineering
these areas
provides
structure and
coordination
to a fragmented
program

POLICY RESPONSE to Emerging Issues

INFORMATION
Surveillance and Exchange

Program Reengineering

PRIORITIZATION (Products & Processes)

MANAGEMENT

structure and coordination

INFORMATION

Surveillance and Exchange

POLICY RESPONSE to Emerging Issues

Process Reengineering

PRIORITIZATION (Products & Processes)

MANAGEMENT

Mfr. Reports - electronic submission

Product Testing

Database Management

Trends & Analysis

Radiation Urgencies

Standards Development

Imports

Research

Reengineering these
processes improves
efficiency

INFORMATION

Surveillance and Exchange

POLICY RESPONSE to Emerging Issues

Current Reengineering Efforts

